	Internal Quality Audits	**53. IT.0017** **Revision: C** **Effective Date:** **September 1999**
Independent Verification & Validation Facility		

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APPROVAL SIGNATURES		DATE
Louis Blazy (original signature on file)	IV&V Facility Director	09/09/99

REVISION HISTORY			
Rev No.	Description of Change	Author	Effective Date
Basic	Initial Release	John Griggs IT/204	08/26/98
A	Format Changes	John Griggs IT/204	09/11/98
B	Consolidation of forms	John Griggs IT/204	01/28/99
C	References to Ames Quality Manual replaced with references to IV&V Facility Quality Manual Updated Section 6.4	John Griggs IT/204	09/10/99

REFERENCE DOCUMENTS	
Document Number	Document Title
53.IT.0000	IV&V Facility Center Quality Manual
53.IT.0014	Corrective and Preventive Action
53.IT.0016	Control of Quality Records
53.IT.0018	Training

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1.0 Purpose

This procedure defines how audits of the IV&V Quality System shall be planned, scheduled and conducted, and their results documented and reported to management to ensure that:

1.1 the quality system effectively implements the IV&V Quality Policy and conforms to the IV&V Facility Center Quality Manual.

1.2 ocumented plans, procedures, and work instructions reflect the organization's current operations, responsibilities, and products.

1.3 personnel, processes, products, and services comply with documented requirements.

1.4 corrective and preventive actions are systematically identified to improve process and quality system performance.

2.0 Scope

This procedure applies to the IV&V Facility Quality System whose processes directly affect the quality of the products and services delivered to customers.

3.0 Definitions and Acronyms

3.1 Audit Manager - The person(s) responsible for managing the internal quality audit program

3.2 Customer - The purchaser, user, or recipient of a product or service provided by the IV&V Facility

3.3 Observation - The auditor's written description of a personally observed condition. While not non-compliant, it could lead to a non-conformance.

3.4 Nonconformity - A lack of compliance to a specified requirement

    3.4.1 Major - a quality system deficiency exists, lack of documented procedures, documented procedures are not being implemented consistently, or a series of minor nonconformities indicated an overall quality system weakness which has an adverse effect upon overall product quality.

    3.4.2 Minor - a defined system exists with an acceptable level of implementation, however, there are minor discrepancies or lapses in discipline.
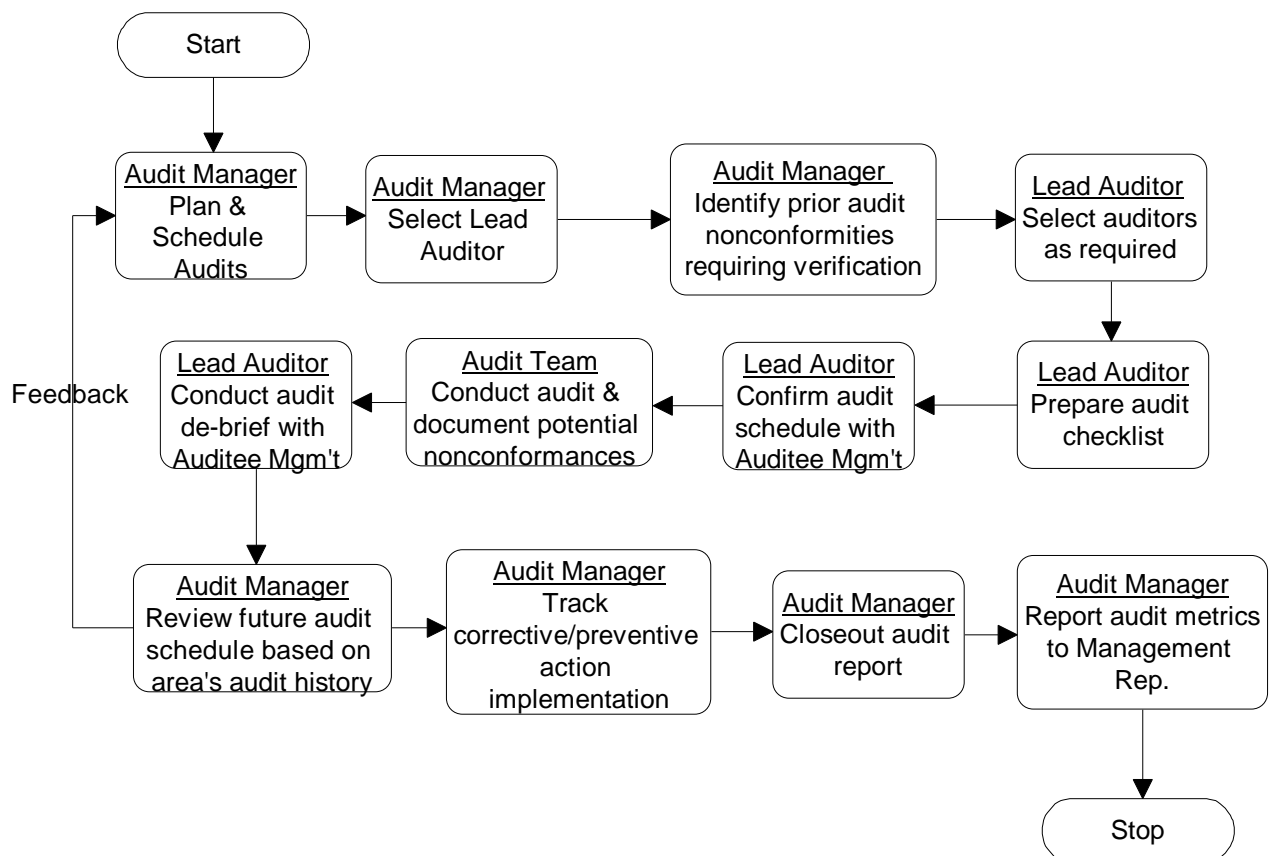
    3.4.3 Observation - an issue noted by the auditor that could lead to a non-conformity if not corrected.

3.5 Recommendation - A proposal to improve the effectiveness of operating practices.

3.6 Commendation - A commendation is written to cite an exemplary system or process of the auditee.

4.0 Flow Chart

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                        ┌──────────┐
                        │  Start   │
                        └────┬─────┘
                             │
                             ▼
            ┌──────────────┐   ┌──────────────┐   ┌──────────────────┐   ┌──────────────┐
            │ Audit Manager│   │ Audit Manager│   │ Audit Manager    │   │ Lead Auditor │
    ┌──────▶│ Plan &       │──▶│ Select Lead  │──▶│ Identify prior   │──▶│ Select       │
    │       │ Schedule     │   │ Auditor      │   │ audit            │   │ auditors as  │
    │       │ Audits       │   │              │   │ nonconformities  │   │ required     │
    │       └──────────────┘   └──────────────┘   │ requiring        │   └──────┬───────┘
    │                                             │ verification     │          │
    │                                             └──────────────────┘          ▼
    │       ┌──────────────┐   ┌──────────────┐   ┌──────────────┐   ┌──────────────┐
    │       │ Lead Auditor │   │ Audit Team   │   │ Lead Auditor │   │ Lead Auditor │
    │       │ Conduct audit│◀──│ Conduct audit│◀──│ Confirm audit│◀──│ Prepare audit│
    │Feedback│ de-brief with│   │ & document   │   │ schedule with│   │ checklist    │
    │       │ Auditee Mgm't│   │ potential    │   │ Auditee Mgm't│   │              │
    │       └──────┬───────┘   │ nonconform.  │   └──────────────┘   └──────────────┘
    │              │           └──────────────┘
    │              ▼
    │       ┌──────────────┐   ┌──────────────┐   ┌──────────────┐   ┌──────────────┐
    │       │ Audit Manager│   │ Audit Manager│   │ Audit Manager│   │ Audit Manager│
    └───────│ Review future│──▶│ Track        │──▶│ Closeout     │──▶│ Report audit │
            │ audit sched. │   │ corrective/  │   │ audit report │   │ metrics to   │
            │ based on     │   │ preventive   │   │              │   │ Management   │
            │ area's audit │   │ action       │   │              │   │ Rep.         │
            │ history      │   │ implementation│  └──────────────┘   └──────┬───────┘
            └──────────────┘   └──────────────┘                             │
                                                                            ▼
                                                                      ┌──────────┐
                                                                      │   Stop   │
                                                                      └──────────┘
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4

5.0 Responsibilities

5.1 The IV&V Facility Director shall:

5.1.1 Assign an Audit Manager to plan, schedule, and manage the IV&V Facility Internal Audit process.

5.1.2 Ensure the Audit Manager has attended an Accredited Lead Auditor Class of the Registrar Accreditation Board.

5.2 The Audit Manager shall perform the following functions:

5.2.1 Audit Preparation

5.2.1.1 Identify auditor training needs in accordance with 53.IT.0018, and:

- ensure all auditors receive formal training in audit methods and objectives.

- ensure Lead Auditor candidates attend an Accredited Lead Auditor class and/or possess sufficient audit experience or on-the-job training as determined by the Audit Manager.

5.2.1.2 Develop the Center's audit schedule and secure the review and approval of the IV&V Facility Director or designee, and ensure:

- the audit schedule covers approximately 12 months.

- audits cover all aspects of the Quality System during that 12-month period.

- the depth and frequency of each audit is based on the prior audit history and operational status of the area to be audited.

5.2.1.3 Assign a sequential audit tracking number to each planned audit.

5.2.1.4 For each area to be audited, select a Lead Auditor and team who are not directly responsible for performance of the activity being audited.

5.2.1.5 Ensure audits are performed in accordance with the approved audit schedule.

5.2.1.6 Reconcile any disagreements between Lead Auditors and audited organizations.

5.2.2 Audit Conclusion and Documentation

5.2.2.1 Review audit reports for clarity and completeness.

5.2.2.2 Distribute audit reports to affected management.

5.2.2.3 Compile and report internal audit metrics to management in accordance with the Process Metrics section of this procedure.

5.2.2.4 Authorize closure of Audit Reports only after associated corrective and preventive actions are opened in the CAR/PAR system.

5.2.2.5 Ensure records are managed in accordance with the Records section of this procedure.

5.3 Each Lead Auditor shall:

5.3.1 Select additional auditors if required by the depth and duration of the planned audit.

5.3.2 Confirm specific audit dates and times with area management.

5.3.3 Prepare audit checklist by either:

5.3.3.1 selecting appropriate sections from Ames Audit Checklist (ARC form 123), or suitable checklist

5.3.3.2 preparing a tailored audit checklist based on prior audit results and specific process or product requirements.

5.3.4 Obtain and review all pertinent documents related to the area being audited.

5.3.5 Plan the audit and divide the audit checklist among any other auditor(s) on the audit team.

5.3.6 Conduct opening meetings and post-audit briefings with area management.

5.3.7 Reconcile any disagreements between auditors and audited organizations, or, when necessary, submit disagreements to Audit Manager for reconciliation.

5.3.8 Review the Nonconformities and Recommendations in each Auditor's Audit Report to ensure these accurately reflect the recorded Observations initialed by management representative and reviewed with the interviewed personnel.

5.3.9 Review any corrections and preventive actions; amend these as necessary to accurately reflect audit Observations.

5.3.10 Within approximately 2 weeks of audit completion, provide the Audit Report and any corrective and preventive actions to the Audit Manager for review.

5.4 Each Auditor and Lead Auditor shall:

5.4.1 Audit the assigned areas using the assigned checklists.

5.4.2 Review the policies, plans, procedures, and work instructions for the area to be audited; determine whether these adequately address all applicable requirements in the Quality Manual.

5.4.3 Interview appropriate personnel and determine whether their actual practices conform to the requirements of the documented policies, plans, procedures, and work instructions.

5.4.4 Document any Observations on the audit checklist.

5.4.5 After the audit, compile all Observations and categorize them as either major/minor Nonconformities, Observations, or Commendations using the IV&V Form 1005.

5.5 Each Audited Organization's Management shall:

5.5.1 Inform area personnel of the time and scope of the audit.

5.5.2 Assign a knowledgeable guide to accompany each auditor.

5.5.3 Provide timely access to processes, products, and documentation needed by the auditor.

5.5.4 Ensure all personnel cooperate with the auditor.

5.5.5 Assist the Lead Auditor in clarifying any issues that come up during the audit or at the post-audit briefing.

5.5.6 Review and understand the Audit Report.

5.5.7 Respond to any corrective or preventive actions in accordance with 53.IT.0014.

6.0 Procedure

6.1 The IV&V Facility audit schedule will be submitted to the Facility management for signature. The schedule will be maintained as a 12 month rolling schedule, updated quarterly.

6.2 The Facility will normally use the Ames audit checklist content, with the format modified for line by line record keeping. The checklist will be tailored to fit the individual audits by the Audit Manager and Lead Auditor for that audit. Open past audit findings and Corrective Action Requests will be factored into the audit planning.

6.3 Individual audits will be tracked by unique identifiers (numbers). Nonconformance reports will be numbered sequentially using the audit number-sequence number.

6.4 Audit nonconformances will be tracked in the Corrective Action system and will be acted upon as follows:

- A major finding will result in immediate action.
- A minor finding may require immediate action.
- An observation does not require immediate action.

7.0 Metrics

Approximately quarterly, the Audit Manager and/or the ISO Manager shall report appropriate internal quality audit metrics to the IV&V Facility Management Representative. Appropriate metrics could include, as a minimum, rolling 12-month trends of the following:

7.1 Percent of audits conducted more than 30 days later than originally scheduled.

7.2 Trend analysis of NCRs identified during audits.

7.3 Percent of NCRs remaining open from previous audits.

8.0 Records

The internal audit process will generate the following records:

Document Name and Identification Number	User Responsible for Record Retention	Retention Requirement	Location
Audit Schedule	Lead Auditor	3 years (min)	Audit Folder/electronic file
Audit Report	Lead Auditor	3 years after closure	Audit Folder/electronic file
IVV Form 1005 (Finding Report)	CAR/PAR Manager	3 years after closure	Audit Folder/electronic file
ISO Certificate	Lead Auditor & Audit Manager	3 years after closure	Audit Folder